Drug and Therapeutics Committee Training Course

Session 6: Evaluating the Cost of Pharmaceuticals

Participant's Guide

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PURPOSE AND CONTENT

This session is designed to provide the participant with basic information concerning pharmacoeconomic principles. The participant will learn the value of a basic cost analysis and how important it is to the DTC in evaluating drugs for the formulary.

Objectives

After completion of this session, participants will be able to—

- Define and understand the different types of cost analysis methods, specifically
  - Cost of illness
  - Cost minimization
  - Cost effectiveness
  - Cost benefit
  - Cost utility

- Understand how to read and assess journal articles concerning an economic study

- Apply session materials to conduct a basic cost analysis for a drug being requested for the formulary

Preparation

Read Participant's Guide.

Further Readings

Bootman, LJ, McGhan, WF, Townsend, RJ. *Principles of Pharmacoeconomics*. Second edition. Cincinnati, OH: Harvey Whitney Books Company. 1996.

Lee, JT, Sanchez, LA. Applied pharmacoeconomics: modeling data from internal and external sources. *Am J Health Syst Pharm* 2000 Jan 15;57(2):146–55.

Sanchez, LA. Applied pharmacoeconomics: evaluation and use of pharmacoeconomic data from the literature. *Am J Health Syst Pharm* 1999 Aug 15;56(16):1630–8.

INTRODUCTION

The Drug and Therapeutics Committee (DTC) is responsible for careful evaluation of new drugs before they are added to the formulary. As discussed in other sessions, this evaluation must involve efficacy, safety, quality, and cost. This session provides information on how to evaluate the cost of a drug—not only its procurement cost but also the cost impact on the entire health care system including the patient. The discussion is important so that the overall evaluation of a drug is complete and the DTC knows all of the cost implications when considering the addition of a new drug. Cost evaluation techniques are used not only for drugs, but also for health care services such as disease management programs.

The drug information literature has an excess of articles, from research to clinical practice, describing the various uses of cost analysis in drug management programs. However, the science of pharmacoeconomics is relatively new and many of the concepts are not well understood by practitioners. When applied appropriately, pharmacoeconomic principles are useful to determine which medication or other intervention will provide the most benefit. Many pharmacoeconomic studies are sponsored by a pharmaceutical company in order to prove economic superiority of its drug over a competitor drug. This is especially true when comparing drugs of similar efficacy and safety. The nature of the pharmacoeconomic discipline allows for the development of a study to meet a particular outcome and, therefore, it is incumbent upon the reader of economic studies to evaluate them carefully.

The quality of pharmacoeconomic studies is frequently poor and it is imperative that the reader of any study take this into consideration. This session concentrates on the basic aspects of pharmacoeconomics so that participants will be able to use key concepts and ideas to evaluate drugs for the formulary. Participants are referred to the key readings to provide more detailed information on the pharmacoeconomic discipline.

KEY DEFINITIONS

Pharmacoeconomics—The description and analysis of the cost of drug therapy to health care systems and society

Cost—The total resources consumed in producing a good or service

Price—The amount of money required to purchase an item

Drug effectiveness—The effects of a drug when used in real-life situations

Drug efficacy—The effects of a drug under clinical trial conditions

COST OF A DRUG

What actually goes into the cost of a drug? The most basic cost of a pharmaceutical is reflected in the acquisition price from a supplier. This is one of the most important aspects in calculating a drug's cost, but it is only a start in the total evaluation. It is becoming more important to look beyond the acquisition cost of a drug and obtain all costs associated with using the drug.

There are three types of costs associated with drugs in a health care system: direct, indirect, and intangible. These three costs, when taken collectively, will give the most comprehensive assessment of actual drug cost.

- Direct costs
  - Acquisition cost of the drug (drug price)
  - Transportation costs
    - Shipping
    - Insurance
  - Inventory carrying cost (supply management cost)
    - Supply personnel salary
    - Storage facilities, including warehouse, refrigerator, freezer
    - Local transportation
  - Costs to prepare and administer drugs
    - Personnel salary (pharmacist, nurse)
    - Equipment and supplies for administration—syringes, gauze, IV sets, filters, pumps, etc.
  - Other direct costs
    - Treating adverse drug reactions
    - Inpatient and outpatient treatment of poor response to drug therapy
    - Emergency room use
    - Hospital costs
    - Laboratory services
- Indirect costs
  - Cost of illness to the patient
  - Lost time from work
- Intangible cost
  - Quality of life

COST-EVALUATION METHODS

Cost of Illness Analysis

Cost of illness (COI) defines the cost involved in treating a particular disease without providing a particular relationship to any type of medical therapy or drug treatment. This is a descriptive analysis and does not provide information as to the appropriateness of therapy. Some of the questions that this type of analysis will answer include—

- What is the current cost of treating a particular disease?
- What is the distribution of the department budget for the various services that are provided?
- What is the cost impact of a particular disease on any given department, e.g., diabetes or acute respiratory diseases on the pharmacy department?

The method of determining the cost of illness is as follows—

- List all direct costs, including drugs, medical services, and laboratory costs
- List all indirect costs, including lost income from illness
- List intangible costs if possible

This kind of cost evaluation is useful to a DTC to have as background information when making recommendations to add drugs to the formulary, and, more important, for the hospital administration to allocate resources to the appropriate departments. If the DTC knows the COI for various illnesses and the frequency of the illness treated, it can compare total cost impact per illness per year. This will help to set priorities for conducting formulary reviews and drug use evaluations.

Table 1 presents a typical COI evaluation.

Table 1. Diabetes Cost of Illness Evaluation (per patient)

COI Parameter	Cost/Year
Diagnosis	$ 500
Initial Treatment	200
Follow-up Treatment	600
Foot Care	100
Optometry Care	150
Nutritionist	100
Pharmacy Services	350
Drug Costs	900
Nursing Services	150
Laboratory Test	300
Laboratory Services	100
Other Hospital Services	450
Total Health Care-Related Costs/Year	***$3,900***
Other Patient-Related Cost	
Transportation Cost for Medical Care	300
Lost Productivity	6,200
Total Patient Costs	***$6,500***
Total Health Care and Patient Costs/Year	***$10,400***

Table 1 shows the enormity of treating a disease like diabetes. Many of these costs will rise and become more profound with time. The total cost of treating a particular disease can then be used to help provide appropriate budgeting to departments based on the incidence of diseases and their impact on a particular department. Diabetes is a very expensive disease for many hospital departments, but particularly for the pharmacy as it requires a significant amount of pharmacist time in dispensing drugs, patient education, and monitoring of drug therapy and, of course, the extremely high drug cost incurred with this disease.

It can also be said that the high cost associated with treating this disease can be decreased by many prevention activities. Almost all effort associated with prevention and better control of diabetes will have a significant positive effect on the disease outcomes and lower cost.

Cost-Minimization Analysis

Cost-minimization analysis (CMA) is a method of calculating drug costs to project the least costly drug or therapeutic treatment. This method of cost evaluation is the one used most often by the DTC to compare different drugs and treatment interventions. Cost minimization can only be used to compare two products that have been shown to be equivalent in therapeutic effect.

Therefore, this method is most useful for comparing generic and therapeutic equivalents or "me too" drugs. This can be difficult for many products, as there may not be a reliable equivalence between the two products. If therapeutic equivalence cannot be demonstrated, then this particular type of cost comparison should not be used.

Cost minimization also reflects the cost to prepare and administer a dose. This would include at least the following:

- Pharmacist and nursing time for preparation
- Laboratory costs
- Cost of any ancillary equipment, including—
  - Syringes
  - Needles
  - IV sets
  - Sterile water for dilution

The method to perform a cost-minimization analysis is as follows—

- Obtain acquisition price.
- Calculate pharmacy, nursing, and physician costs (if they contribute significantly to the cost of using the drug).
- Calculate cost of supplies.
- Calculate cost of laboratory services (if a significant cost is involved).
- Calculate costs of any other significant factors.

Table 2 is an example of a cost-minimization analysis of two injectable antibiotics for treating meningitis.

Table 2. Sample Cost-Minimization Analysis (based on per course of treatment)

Cost Centers	Drug A	Drug B
Acquisition Price	$8.00	$15.00
Pharmacist Salary	2.50	1.50
Nursing Salary	2.50	2.00
Supplies	9.00	2.25
Laboratory Services	4.00	1.00
Total	$26.00	$21.75

The cost-minimization analysis in Table 2 shows that these two drugs are similar in cost. However, just looking at acquisition cost of the drug would have shown that Drug A was less costly and probably preferred if all other criteria for selection were equal. Completing the cost-minimization analysis provides information indicating that the real cost of the two drugs is significantly different from the acquisition price and that Drug B has a lower overall cost.

Cost-Effectiveness Analysis

Cost-effectiveness analysis (CEA) is used when there is a single measurable dimension of effectiveness for both treatments and these alternative treatments do not have the same effectiveness. Cost-effectiveness methodology is best utilized when it is necessary to measure both costs and clinical outcome of the drugs as measured in health care improvements and outcomes from the use of the drug.

As shown above, obtaining the price of a drug is relatively straightforward and involves looking at the cost of procurement, ancillary supplies, and services to administer the drug. Obtaining the cost information on treatment is difficult and frequently not accurate. Accurate information is necessary in order to successfully perform this type of analysis. As a general rule, the effectiveness component of this evaluation is determined by one measurable outcome. Some examples of measurable outcomes or health care improvements for specific conditions are as follows:

- Hypertension—blood pressure measurements
- Diabetes—glycosylated hemoglobin, blood glucose results
- Coronary heart disease—angina attacks
- Urinary tract infections—incidence of infections, cured infections
- Seizures disorders—seizures
- HIV/AIDS—CD4 counts
- Heart failure (and most other diseases)—disability-adjusted life years (DALYs)

Table 3 displays the preliminary information needed to perform a cost-effectiveness study of two drugs used in the treatment of diabetes.

Table 3. Sample Preliminary Cost-Effectiveness Analysis

Drug A	Cost/Month	Drug B	Cost/Month
Acquisition Cost	$20.00	Acquisition Cost	$10.00
Administration Cost	2.00	Administration Cost	2.00
Lab Cost	8.00	Lab Cost	16.00
ADR Cost	4.00	ADR Cost	8.00
Physician Visits	10.00	Physician Visits	20.00
Total Cost	$44.00	Total Cost	$56.00

The cost comparison at this point in the analysis shows that Drug A is less costly than Drug B by 22 percent. This lower cost is despite the high acquisition cost of $20.00/month, twice that of Drug B. The cost savings, in this example, come from Drug A's lower adverse drug reaction (ADR) rate and subsequent lower laboratory and physician costs.

A cost-effective ratio can now be calculated based on the cost of the drug and the targeted medical endpoint. The numerator will be the cost in monetary units and the denominator will be the effectiveness expressed in the measurement of reportable units. In the above example we could calculate the cost-effective ratio as follows:

Drug A
Cost of Drug A = $44.00
Effectiveness Measure = Reduction in glycosylated hemoglobin
Effectiveness of Drug = Average decrease of 1.5% glycosylated hemoglobin

Cost-Effective Ratio for Drug A:

$44.00/1.5 or $29.33 for a 1% decrease in glycosylated hemoglobin

Drug B
Cost of Drug B = $56.00
Effectiveness Measure = Reduction in glycosylated hemoglobin
Effectiveness of Drug = Average decrease of 0.8 % of glycosylated hemoglobin

Cost-Effective Ratio for Drug B:

$56.00/0.8 or $70.00 for a 1% decrease of glycosylated hemoglobin

Therefore, in this example Drug A is the most efficacious drug clinically and is the most cost-effective. The determining factor here is the improved outcome with Drug A, which makes it more cost-effective even though it has a substantially higher acquisition cost.

Summary of Steps to Accomplish CEA

Using the example above, the following is a stepwise approach to accomplishing the cost-effectiveness evaluation:

1. Clearly define the objectives—Which drug is the most cost-effective alternative?

2. List the methods to achieve the objective—Use of Drug A or Drug B.

3. Identify and measure the costs of each option:

    - Acquisition costs
    - Laboratory monitoring
    - Physician costs
    - Pharmacist costs
    - All other significant drug costs

4. Identify and measure the clinical outcome of each option—Decreased glycosylated hemoglobin (as an intermediate measure of diabetes control and outcome).

5. Establish cost-effective ratio for each option—Preferred drug is the one with the lower cost per unit of health improvement.

6. Perform sensitivity analysis on the conclusions—Sensitivity analysis is used to determine how sensitive the results of a study are to different variables within the evaluation. In this type of analysis variables can be changed and the cost-effectiveness study is repeated to see if the results supporting the original conclusion change. Examples of variables from this cost-effectiveness analysis are cost of physician visits, price of Drugs A and B, cost estimate of ADRs as well as the number of ADRs experienced, and laboratory tests. In a sensitivity analysis, different estimates of cost can be applied to the variables and the analysis performed to confirm or refute the original results.

Cost-Benefit Analysis

In cost-benefit analysis (CBA), there is a calculation of the cost of the drug and the net savings in cost associated with the benefit of the drug to the patient. Unlike cost-effectiveness analysis, where comparable drugs are analyzed for the same outcome, this analysis uses different treatments and benefits. These benefits could involve a number of parameters, including increased work productivity, patient satisfaction, and productivity at home. Benefits would even include increased productivity and job satisfaction of physicians and pharmacists as a result of using this drug. All benefits must be translated into monetary units in order to make the comparison with cost.

Arriving at a cost-benefit ratio is difficult but may provide important information about true cost to the patient. By definition, cost-benefit analysis is the ratio of the total costs of each therapy to the amount of money saved by using this particular therapy (benefits provided). Table 4 presents an example of a cost-benefit analysis.

Table 4. Sample Cost-Benefit Analysis

Cost Center	Cost
Patient Cost	
Drug Acquisition	$ 50.00
Laboratory Monitoring	20.00
Supplies to Administer	15.00
Personnel Cost	7.00
Hospital Cost	150.00
Total Patient Cost for Drug	*$242.00*
Patient Benefits	
Work Productivity	$250.00
Patient Satisfaction	100.00
Reduced Hospitalization Days	75.00
Total Benefit of Drug	*$425.00*
Net Benefit of Drug	$183.00 (Benefit minus identified cost)
Benefit to Cost Ratio	1.8 to 1 (Benefit divided by cost)

In this example, the cost of the drug is $242.00 while the cost of benefits is estimated to be $425.00. The benefit to cost ratio would be 1.8 to 1. This method could then be used to calculate a ratio for other drugs to make a final comparison when deciding on a specific drug or service for the formulary.

Because of the difficulty in obtaining valid estimates of benefits and the value of those benefits, this type of cost comparison may prove to be problematic.

Cost-Utility Analysis

Cost-utility analysis (CUA) is used to determine cost as it relates in terms of utilities, especially quantity and quality of life (QOL). This is a controversial methodology because it is difficult to put a value on a level of health status or improvement in health status as measured by different individuals or societies. Unlike cost-benefit analysis, cost-utility analysis is used to compare two different drugs or procedures when the benefits of these may be different. Cost utility has been successful in describing costs associated with health care programs, such as specialty clinics or a pharmacy-based lipid clinic, but not necessarily individual drug entities.

One method to measure a patient's quality of life is the quality-adjusted life year or QALY. This measurement of outcome in a patient's life can be utilized to assess how diseases affect the outcome. For example, if a disease state reduces a person's life span by 25 percent, this could be interpreted to decrease the quality of life per year by 25 percent. This could then be calculated as .25 QALY each year. Cost utility attempts to compare the cost for each drug in relation to its effect on QALY.

To obtain information on the quality of life, there are several measures that are considered reliable indicators of a patient's quality of life. Questionnaires can be administered to the patient and then an assessment made concerning the patient's quality of life as it relates to the disease process and medical treatment provided.

Discounting

Discounting is used in cost evaluations to establish present value of a future benefit. This method is necessary to take into account the effects of inflation and aging (life span). Actual benefits of a drug today or this year would not have the same value 5 to 10 years from now. Discounting is an important concept to give validity to the pharmacoeconomic calculations that have benefits ranging over prolonged periods of time.

Discounting, like many aspects of the pharmacoeconomics field, is very controversial. The rate of discounting varies from country to country and depends on the particular investigator studying the drug. The discount has to be tied to the economics of the country where the drug or service would be provided.

The appropriate rate of discounting is not known for sure in any pharmacoeconomic study and, consequently, any rate used will have a dramatic effect on the results of the economic study. In the United States, the discount rate is frequently set at 5 percent. The formula for calculating future cost to reflect current value is as follows:

$$PV = 1/(1+r)^{N}$$

PV = present value
r = discount rate
N = years of benefit to be measured

Sensitivity Analysis

Sensitivity analysis is used to measure how different assumptions made in the determination of a particular cost analysis will affect the conclusions. Sensitivity analysis also determines how sensitive the results of a study are to different variables within the evaluation. In this type of analysis, variables can be changed and the cost-effectiveness study repeated to see if the results supporting the original conclusion change. Sensitivity analysis can be used in cost-minimization, cost-effectiveness, cost-benefit, and cost-utility studies.

Examples of variables in a cost analysis study include cost of physician visits, price of drugs, cost estimate of ADRs as well as the number of ADRs experienced, laboratory tests required in the treatment, and duration of treatment. In a sensitivity analysis, different estimates of cost can be applied to the variables and the analysis performed to confirm or refute the original results.

EVALUATING PHARMACOECONOMIC STUDIES

Cost analysis of a new drug requested for the formulary is both necessary and controversial. While costs are very important, many people would argue that cost should take a low priority in developing criteria for selecting a drug. However, few would doubt in this day and age that the cost of a drug is indeed very important and that a realistic methodology is needed to determine the true cost of a drug.

How cost is analyzed and the determination of how useful these cost estimates are is problematic. The field of pharmacoeconomics is new and expanding. Performing a comprehensive cost evaluation is beyond the means of most practitioners and most health care systems. Simple cost evaluations can be accomplished including cost-minimization and cost-effectiveness, but we must rely on the clinical literature to provide us with information concerning more comprehensive cost evaluations of drugs and medical services.

Unlike clinical studies that involve drug comparisons for efficacy, there is no “gold standard” for pharmacoeconomic studies. There are several different methods of performing these studies and the outcomes are highly dependent on how the analysis was performed.

Advantages to using the clinical literature for cost analysis include the following:

1. If the study is relevant to the reader's practice setting, then the study will provide quick information for the busy practitioner.

2. Studies published in reputable journals are generally (not always) peer reviewed; consequently, the information provided has been reviewed for appropriate methodology and conclusions. This does not guarantee that a study is complete and accurate, only that there has been an evaluation of the methodology used.

3. There may be more than one study of the drug or therapy in question, resulting in more than one economic evaluation of the same entity—if the studies agree, then this will serve to strengthen conclusions about the economic questions.

Disadvantages to using the pharmacoeconomic literature are numerous and readers of this literature must be careful when interpreting results.

1. A significant problem is the applicability of a study for one's home country or community—what may make sense economically in one area of the world may not be applicable in other areas.

2. The randomized controlled study is the most reliable drug study design. Unfortunately the rigorous nature of a clinical trial frequently does not reflect what will happen in other locations where there are not the same constraints of the study, i.e., blinding, monitoring, laboratory testing, intense medical follow-up, etc.

3. The rush to conduct pharmacoeconomic studies has resulted in variations in the quality of many studies performed. Problems include using incorrect methodology, arriving at incorrect conclusions, and defining important pharmacoeconomic terms incorrectly.

4. Many studies are conducted by pharmaceutical companies. There is always the possibility of bias being introduced concerning the information about the company's drug.

5. Negative outcome research seldom gets into the literature. This again may relate back to the sponsor of the study, which may want to suppress any results that are not useful in promoting a particular drug.

The literature is full of pharmacoeconomic evaluations that do not adhere to rigorous principles of clinical testing. Readers must therefore interpret data cautiously. The following information provides a reader with some fundamentals concerning the evaluation of pharmacoeconomic literature. Some fundamental questions that a reader must ask about a cost study are—

- Are the patients selected for the study similar to those in your community?
- Are costs of the drugs fully described?
- Are costs of benefits fully disclosed?
- Is the study applicable to your setting?

The approach presented below will provide for a comprehensive evaluation of the literature. This list (adapted from Sanchez, AJHP 1999[*]) will give you the necessary information for making a more informed decision concerning studies involving pharmacoeconomic materials.

- Study objective
  - Is the economic question clear and concise?
  - Is the outcome of interest measurable?

- Study perspective
  - What is the perspective of the analysis (i.e., patient, hospital, third party payer)?
  - Is the perspective relevant, given the scope of the problem?

- Type of pharmacoeconomic methods
  - What was the economic method used?
  - Was the economic method appropriate and actually used?

- Study design
  - What was the study design?
  - What were the data sources?
  - Was the evaluation suitable if carried out in a clinical trial?

- Choice of intervention
  - Were all of the appropriate alternatives (alternative treatments that may be compared to the study drugs) considered and described?
  - Are the alternatives relevant to the perspective and nature of the study?

- Costs and consequences
  - What are the costs and consequences (outcomes)?
  - Were all of the important costs for each alternative identified, including negative outcomes?
  - Are the costs and consequences relevant to the perspective chosen?

- Discounting
  - Were any costs and consequences occurring in the future discounted to reflect their current value?
  - What was the discount rate?

- Results
  - Are the results accurate and useful for the DTC?
  - Were the appropriate statistical analyses used?
  - Are all the assumptions and limitations of the study discussed?

[*] Sanchez, LA. Applied pharmacoeconomics: evaluation and use of pharmacoeconomic data from the literature. *Am J Health Syst Pharm* 1999 Aug 15;56(16):1630–8.

- Sensitivity analysis
  - Was a sensitivity analysis performed?
  - Were the ranges for important variables tested?
  - Were the appropriate variables verified?
  - Do the findings follow the anticipated trends?

- Conclusions
  - Are the conclusions of the study justified?
  - Is it possible to extrapolate the conclusions to your daily practice?

- Sponsorship
  - Was the study sponsored or conducted by industry?
  - Was there any bias due to the sponsorship of the study?

ACTIVITIES

Activity 1. Cost Analysis of a New Antibiotic

Your DTC is faced with the prospect of adding a new antibiotic for treating meningitis in children. This antibiotic, Cephlasporacillin, is an established drug but has never been added to the formulary because of its high cost. The antibiotic appears to be at least as effective (from a literature evaluation) as other formulary antibiotics (combination of ceftriaxone and ampicillin) but is thought to be safer by one member of the medical staff. The DTC chairman is very interested in reviewing this particular drug, but does not want to take on another high-cost drug without some proven benefit. Other information about the drugs includes—

- Cephlasporacillin
  - Anticipated use: 3,000 doses per year
  - Dose: 1 gm IV every 24 hours
  - Procurement price: $22.50/dose

- Ampicillin injection
  - Dose: 1 gm every 4 hours
  - Procurement price: $0.50/dose

- Ceftriaxone
  - Dose: 1 gm every 12 hours
  - Procurement price: $6.00/dose

Assess the cost of this antimicrobial by using the cost-minimization method. If other information is needed, please contact the instructor.

Activity 2. Cost Analysis of Antibiotic Ear Drops

Your DTC is considering the addition of an antibiotic eardrop to the formulary. OticRx is available at a cost of $6.50 per treatment. A literature review shows that it is effective in approximately 80 percent of treatment courses. Cortispor has a cost of $7.90 for each treatment and has been found to be 90 percent effective. The drug would be used for approximately 1,000 patients each year.

- Evaluate these two products using a cost-effective approach.

- What other important information is necessary before making a decision on the cost-effectiveness of these two drugs?

SUMMARY

Cost analysis is an important component in evaluating the usefulness of a drug for the formulary. A simple determination of a drug price is frequently inadequate for determining the actual cost of a drug to the health care system.

Performing basic economic comparisons can be done by the DTC. Some commonly used analyses include cost of illness, cost-minimization, and cost-effectiveness studies. Other studies usually require more sophisticated systems and a significant amount of time to develop, interpret, and perform the study. The DTC can also utilize pharmacoeconomic information from clinical trials or reasonable extrapolations of these trials.

It is likely that health care practitioners will be faced with the need to conduct or evaluate drug costs in the future and the health care system will demand that these be carefully considered before adding a new drug to the formulary.